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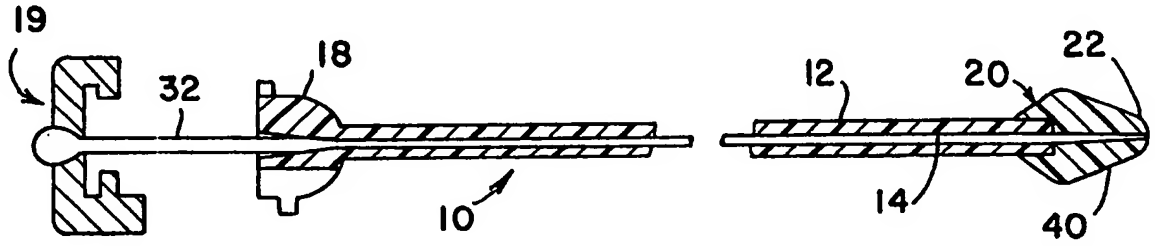
(54) Title: TRACKING GUIDEWIRE



(57) Abstract

A guidewire (10) for placement within a blood vessel for penetrating an occlusion therein. The guidewire (1) comprises a length of flexible wire (12) having a lumen extending therethrough. The distal end of the guidewire (10) is generally arcuate and has a diameter greater than that of the wire (12) immediately proximal thereto. A flexible stylet (32) substantially the same length as the flexible wire (12) may be disposed within the lumen of the wire (12). The stylet (32) and the guidewire (10) have locking means (19, 18), such as Luer locking threads. In operation, the arcuate distal end of the guidewire (10) is positioned in the blood vessel against an occlusion, and a dottering action is thereafter provided whereby the arcuate distal end of the guidewire (10) repeatedly impinges on the occlusion until penetration of the occlusion occurs.

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TRACKING GUIDEWIRE

This is a continuation-in-part of application Serial No. 07/851,224 filed March 12, 1992 which is a continuation of application Serial No. 07/535,932 filed June 11, 1990.

Background of the Invention

This invention relates generally to a tracking guidewire, and in particular to an occlusion-penetrable guidewire having a lumen throughout its entire length into which a stylet can be inserted. Preferably the distal end portion of the guidewire is arcuate and has a diameter greater than that of the immediately proximal wire.

Vessel entry for treatment of certain untoward health conditions is a common practice. Such entry can include insertion into a blood vessel of a guidewire whose distal end is expected to reach a certain site within the body and have utility thereafter as required. Many times, however, a blood vessel may be completely or almost completely occluded, thereby rendering it substantially impossible to advance a guidewire there beyond to a designated site without first employing a separate procedure to remove the occlusion.

It is therefore a primary object of the present invention to provide a guidewire having a lumen running its entire length and a distal end portion capable of penetrating a vascular occlusion. Another object of the present invention is to provide such a guidewire wherein the tip of the distal end portion is arcuate and the diameter of the distal end portion is greater than that of the immediately proximal wire. Yet another object of the present invention is to provide a guidewire assembly wherein a stylet can be removably

inserted into the length of the guidewire lumen to thereby enhance guidewire structure. These and other objects will become apparent throughout the description which now follows.

Summary of the Invention

The present invention is a guidewire for placement within a blood vessel for penetrating an occlusion in the vessel. The guidewire comprises a length of flexible wire having a concentric lumen running its entire length. At its proximal end, the wire has an opening to the lumen. At its distal end, the wire has an arcuate tip with a diameter greater than the diameter of the wire immediately proximal thereto.

In addition, the guidewire may include a flexible stylet substantially the same length as the guidewire that is removably inserted into the lumen of the guidewire. Such stylet placement provides a greater stiffness and structural integrity to the guidewire.

Finally a method of penetrating an occlusion in a blood vessel is disclosed. The method comprises inserting the guidewire into an occluded blood vessel. Initially, the stylet is positioned in the lumen of the guidewire so that it extends into the arcuate tip portion. When the guidewire contacts the lesion site, the stylet is removed from at least the distal end of the guidewire. This allows the arcuate tip to center itself at the proximal portion of the lesion site. Thereafter, the stylet is fully inserted into the arcuate tip of the guidewire. A dottering action, i.e. a back and forth movement to impinge the arcuate tip against the lesion, is provided to the guidewire. This dottering action is carried out for a sufficient period of time whereby the repeated impingement upon the occlusion results in penetration thereof. After the

distal end of the guidewire has passed through the occlusion, the stylet can be withdrawn and a contrast medium can be injected into the lumen to confirm guidewire positioning within the vessel.

Brief Description of Drawings

Presently preferred embodiments of the invention are illustrated in the accompanying drawings in which like reference numerals refer to like parts throughout and in which:

Figure 1 is a side elevation view of one embodiment of the guidewire of this invention without a stylet inserted therein;

Figure 2 is a side elevation view partially in section of one embodiment of the guidewire of this invention with the stylet inserted therein;

Figure 3 is a side elevation view of a stylet;

Figure 4 is a partial side elevation view of a second embodiment of a distal end of the guidewire of this invention;

Figure 5 is a partial side elevation view of a third embodiment of a distal end of the guidewire of this invention;

Figure 6 is a side elevation cross-sectional view of a fourth embodiment of the guidewire of this invention with a stylet partially inserted therein;

Figure 7 is a side elevation cross-sectional view of the fourth embodiment of the guidewire of this invention with a stylet fully inserted therein; and

Figures 8, 9 and 10 are side elevation views of a partially occluded blood vessel with the guidewire of this invention being used to effect penetration through the occlusion.

Detailed Description of Preferred Embodiments

The guidewire 10 of this invention comprises a

length of flexible wire 12 having a lumen 14 running the entire length of wire 12. A proximal end hub 18 opens to lumen 14. The distal end 20 of wire 12 has an arcuate tip 22 with a diameter greater than the diameter of wire 12 immediately proximal to distal end 20. Guidewire 10 can be conventionally constructed of metal core, and is preferably constructed of metal coils.

A flexible stylet 32, as shown in Figure 3, may be disposed within lumen 14 of wire 12. Stylet 32 is substantially the same length as wire 12 so that stylet 32 preferably does not extend beyond distal end 20 of arcuate tip 22. The distal end 35 of stylet 32 may be tapered as shown in Figures 2 and 3. In addition, stylet 32 has a proximal end member 34 whose shape is complementary to the interior wall 36 of hub 18. Preferably a locking means 19, such as conventional Luer locking threads, is used to securely maintain stylet 32 within lumen 14. Luer locking threads also provide releasability for withdrawal of stylet 32 as required. See Figures 6 and 7. Stylet 32 can be constructed of metal or polymer core, and is preferably constructed of metal.

As earlier noted, distal end 20 of wire 12 has an arcuate tip 22 and has a diameter which is greater than that of wire 12 immediately proximal thereto. Three non-limiting examples of preferred shapes of distal end 20 are illustrated in the Figures. Specifically, Figures 1, 2 and 6-10 show an arrowhead shape 40; Figure 4 shows an elliptical shape 42; and Figure 5 illustrates a tear-drop shape 44. It is to be understood, of course, that shapes other than those illustrated can be employed as long as an arcuate tip is provided to thereby enhance physical intrusion of an

occlusion. The various shapes of the respective distal ends are attained in the manufacturing process which can include EDM machining and grinding.

In operation, guidewire 10, and in particular arcuate tip 22 and distal end 20, functions to penetrate an occlusion in a blood vessel. The user inserts guidewire 10 with stylet 32 fully inserted into distal end 20 into a blood vessel and positions arcuate tip 22 against the proximal wall of an occlusion. See Figure 8. Once placed, stylet 32 is withdrawn from distal end 20. This gives guidewire 10 more flexibility and allows the user to easily center distal end 20 against the occlusion. See Figure 9. At this point, stylet 32 can be fully inserted into distal end 20. See Figure 10. Guidewire 10 is then subjected to a dottering action, i.e. a repeated back and forth movement, by the user to effectuate a repeated impinging action upon the occlusion by arcuate tip 22 and distal end 20. This dottering action is continued for a period of time sufficient to penetrate the entire length of the occlusion and thereby permit continued travel of guidewire 10 itself or of other apparatus through the occlusion. Once distal end 20 of guidewire 10 is through the occlusion, stylet 32 can be removed from lumen 14 and a contrast medium can be injected into lumen 14 to thereby confirm the true position of distal end 20. Of course, guidewire 10 may be used to cross an occlusion without stylet 32 located in lumen 14.

While an illustrative and presently preferred embodiment of the invention has been described in detail herein, it is to be understood that the inventive concepts may be otherwise variously embodied and employed and that the appended claims are intended

to be construed to include such variations except insofar as limited by the prior art.

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CLAIMS

WHAT IS CLAIMED IS:

1. A guidewire (10) for placement within a blood vessel for penetrating an occlusion therein comprising a flexible wire (12) having a proximal end and a distal end and a lumen (14) extending through the wire (12) wherein the distal end of the wire (12) has an arcuate tip (22) and has a diameter greater than the diameter of the wire (12) immediately proximal thereto and wherein the proximal end of the wire (12) has a first locking means (18) for releasably securing a proximal end of a stylet (32) thereto.

2. The guidewire (10) of claim 1 further comprising a flexible stylet (32) having a proximal end and a distal end, the proximal end having a second locking means (19) for locking the proximal end of the stylet (32) to the first locking means (18) and extending substantially the length of the wire (12).

3. A method of penetrating an occlusion in a blood vessel, the method comprising:

a) providing a guidewire (10) comprising

i. a flexible wire (12) having a proximal end and a distal end and a lumen (14) extending through the wire (12) wherein the distal end of the wire (12) has an arcuate tip (22) and has a diameter greater than the diameter of the wire (12) immediately proximal thereto and wherein the proximal end of the wire (12) has a first locking means (18) for releasably securing a proximal end of a stylet (32) thereto; and

ii. a flexible stylet (32) having a proximal end and a distal end, the proximal end having a second locking (19) means for locking the proximal end of the stylet (32) to the first locking means (18)

and extending substantially the length of the wire (12);

b) inserting the guidewire (10) into the blood vessel and positioning the distal end of the wire (12) against the occlusion;

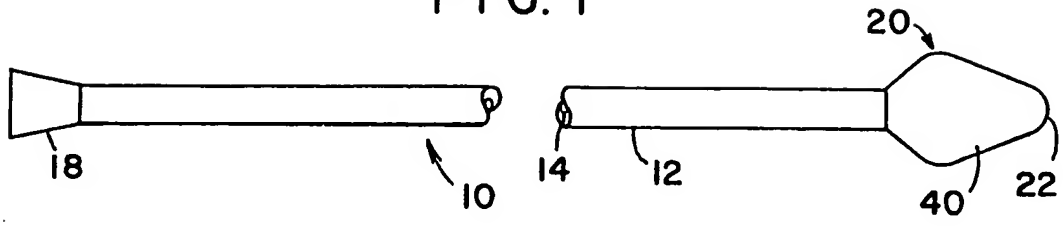
c) centering the distal end of the wire (12) at the occlusion;

d) inserting the stylet (32) into the lumen (14) so the distal end of the stylet (32) is disposed within the distal end of the wire (12); and

e) providing a dottering action to the guidewire (10) for a sufficient period of time whereby the distal end of the wire (12) repeatedly impinges upon the occlusion until said occlusion is penetrated.

4. The method of claim 3 wherein the stylet (32) is inserted into the lumen (14) prior to inserting the guidewire (10) into the blood vessel and the stylet (32) is removed from at least the distal end of the wire (12) before centering the distal end of the wire (12) at the occlusion.

FIG. 1



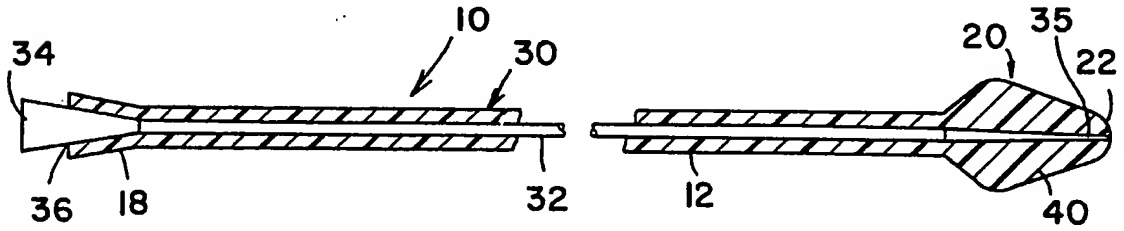


FIG. 2

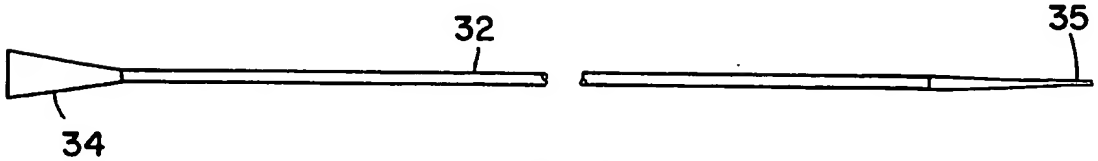


FIG. 3

FIG. 4

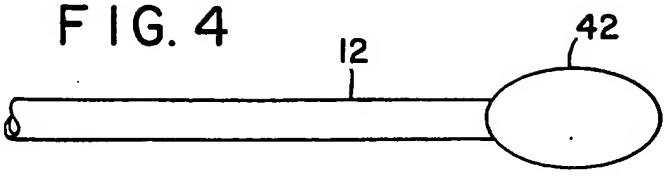


FIG. 5

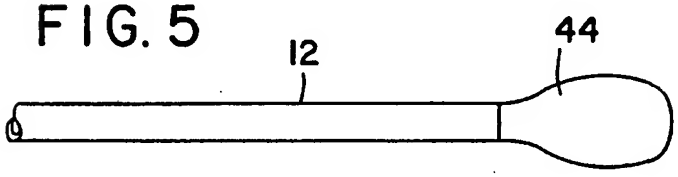


FIG. 6

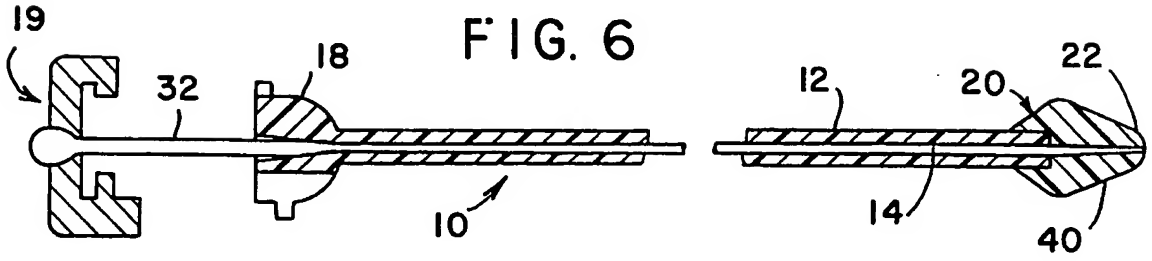


FIG. 7

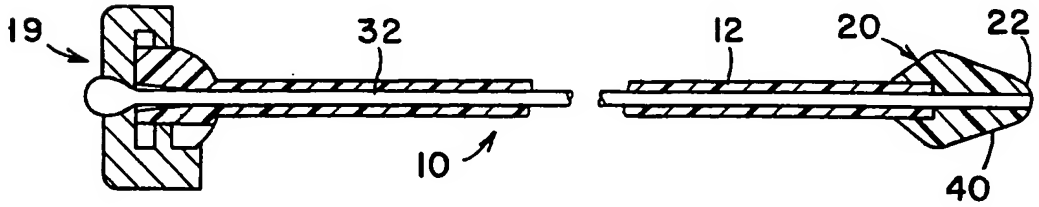


FIG. 8

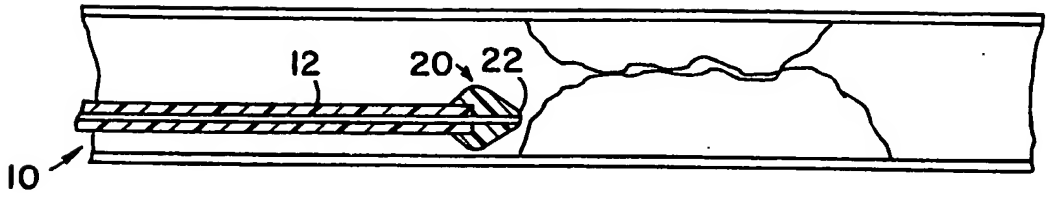


FIG. 9

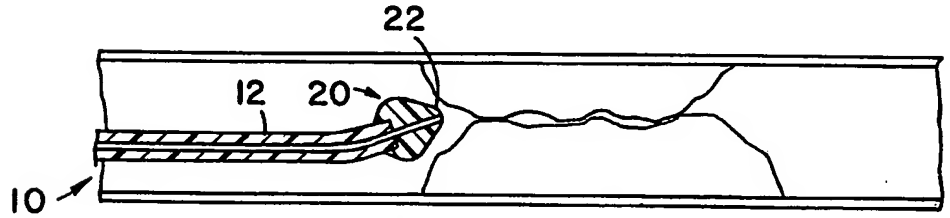
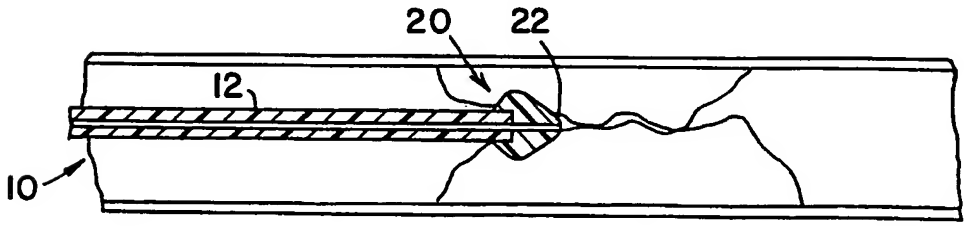


FIG. 10



INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 93/11794

A. CLASSIFICATION OF SUBJECT MATTER
IPC 5 A61M25/01 A61M29/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 5 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO,A,91 19528 (SCHNEIDER) 26 December 1991 cited in the application see page 3, line 28 - line 32; claims 1,2; figure 2	1,2
A	US,A,1 920 006 (DOZIER) 25 July 1933 see page 2, line 35 - line 44; figures 1,3	1,2
A	EP,A,0 242 985 (SHERWOOD) 28 October 1987 see page 5, line 17 - line 29; figures 1,3	1,2
A	US,A,4 793 363 (AUSHERMAN ET AL.) 27 December 1988 see abstract; figures 3,4,7	1,2

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 March 1994	19.04.94

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Moers, R

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

i. .national application No.

PCT/US 93/ 11794

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 3 and 4
because they relate to subject matter not required to be searched by this Authority, namely:
Method for treatment of the human or animal body by surgery.
Please see Rule 39.1(iv) PCT.

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte. nal Application No
PCT/US 93/11794

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A-9119528	26-12-91	AU-B-	640493	26-08-93
		AU-A-	7960491	07-01-92
		DE-U-	9190089	11-02-93
		EP-A-	0538271	28-04-93
US-A-1920006		NONE		
EP-A-0242985	28-10-87	AU-B-	590914	23-11-89
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		DE-A-	3776587	19-03-92
		JP-A-	62243566	24-10-87
		US-A-	4834709	30-05-89
US-A-4793363	27-12-88	NONE		